AUG 1 1 2005

K050984

SYBRON DENTAL SPECIALTIES

Section III - 510(k) Summary of Safety and Effectiveness

Submitter:

Sybron Dental Specialties, Inc.
1717 W. Collins Avenue
Orange, California 92867
(714) 516-7484 - Phone
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Colleen Boswell - Contact Person

Date Summary Prepared: April 2005

Device Name:

- Trade Name - *Bioplant*
- Common Name - Synthetic Bone Grafting Material
- Classification Name - Unclassified

Devices for Which Substantial Equivalence is Claimed:

- Heraeus Kulzer, *Ostim Bone Grafting Material*
- Biomet Inc., *HTR- MX*

Device Description:

Bioplant is a synthetic polymer bone void filling material which, due to its porosity characteristics, is capable of supporting ingrowth of bony tissue. This non-resorbable and radio-opaque material is used to fill, augment or reconstruct periodontal or bony defects of the oral and maxillofacial region. The material consists of poly methylmethacrylate (PMMA) beads coated with poly hydroxyethyl methacrylate (PHEMA) to increase hydrophlicity of the porous structure, a thin layer of barium sulfate for radio-opacity, and calcium hydroxide for hydrophilicity and to promote bone growth around the PMMA beads. The average particle size of the beads is 750 microns. The product is sterilized using gamma radiation.

Intended Use of the Device:

The intended use of *Bioplant* is to fill, augment or reconstruct periodontal or bony defects of the oral and maxillofacial region in the following indications: 1) To maintain and restore the bony alveolar ridge after extraction of tooth-roots. i.e., Ridge preservation/Socket grafting, 2) To restore infra-bony defects caused by destructive periodontal disease, i.e., 2-3 wall defects/Class I, II and III furcations, 3) To augment bony defects, i.e., apicoectomies, cystic formation or tumor removal, 4) Ridge augmentation to

restore the height and/or width of severely atrophied alveolar ridges, 5) Augmentations in the maxillary sinus, 6) Bone voids associated with implant replacement.

Substantial Equivalence:

Bioplant is substantially equivalent to other legally marketed devices in the United States. *Bioplant* functions in a manner similar to and is intended for the same use as the product *Ostim Bone Grafting Material* and *Bioplant* functions in a manner similar to and is composed of the same materials as *HTR-MX* marketed by Heraeus Kulzer and Biomet Inc., respectively.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 1 2005

Kerr Dental Materials Center
C/O Ms. Colleen Boswell
Director, Corporate Compliance
Division of Sybron Dental Specialties, Incorporated
1717 West Collins Avenue
Orange, California 92867

Re: K050984
Trade/Device Name: BIOPLANT
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone grafting material
Regulatory Class: II
Product Code: LYC
Dated: July 28, 2005
Received: July 29, 2005

Dear Ms. Boswell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K050984

Indications for Use

510(k) Number (if known):

Device Name: *Bioplant*

Indications For Use:

Bioplant is a synthetically derived, spherical material which is intended to fill, augment or reconstruct periodontal or bony defects of the oral and maxillofacial region in the below indications.

1) To maintain and restore the bony alveolar ridge after extraction of tooth-roots, i.e., Ridge preservation/Socket grafting;
2) To restore infra-bony defects caused by destructive periodontal disease, i.e., 2-3 wall defects/Class I, II and III furcations;
3) To augment bony defects, i.e., apicoectomies, cystic formation or tumor removal;
4) Ridge augmentation to restore the height and/or width of severely atrophied alveolar ridges;
5) Augmentations in the maxillary sinus;
6) Bone voids associated with implant placement.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

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